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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,665	12/16/2002	Philip O. Livingston	2653/56	9377
26646	7590	03/22/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			SEETHARAM, SARASWATHY	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/070,665	<b>Applicant(s)</b> LIVINGSTON ET AL.	
	<b>Examiner</b> Saraswathy Seetharam, PhD	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-81 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature that appears to In the instant case claim 1 is not unobvious over the prior art as evidenced by Jennings et al.(J Immunology ,1986,137: 1708-1713) .Jennings et al teach conjugation of N propionylated B derivatives of group B meningococcal polysaccharides to tetanus toxoid that when injected into mice induced antigen specific IgG antibodies. (see entire document). Therefore, one of ordinary skill would be motivated to use different toxins with different antigens to produce conjugates and administer it in an adjuvant setting in cancer therapy. Because the claims are nonobvious over the prior art, the claim lacks a special technical feature which contributes to the art.

Accordingly the groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-20, drawn to an immunogenic composition, a modified composition, comprising an  $\alpha$  (2-8)-polysialic acid carrier conjugate and a saponin, wherein the said conjugate comprises one or more  $\alpha$  (2-8)-polysialic acid polymers covalently linked to immunogenic carrier, keyhole limpet hemocyanin (KLH), wherein the number of median number of sialic acid units in each of the polymers is at least is about 10 and a vaccine comprising an effective amount

Art Unit: 1642

of said immunogenic composition to induce specific antibodies for polysialic acid moieties of embryonal neural cell adhesion molecule (N-CAM) and a pharmaceutically acceptable vehicle.

Group II, claims 21- 38, drawn to a method of stimulating antibody production specific for polysialic acid of an embryonal N-CAM.

Group III, claims 39-59, drawn to treating small cell lung cancer or neuroblastoma in a subject.

Group IV, claims 60-77, drawn to a method of stimulating immunity against group B N. meningitides or E.coli KI .

Group V, claims 78 and 79, drawn to a method of treating small cell lung cancer or neuroblastoma in a subject comprising the administration of human or humanized antibodies prior to, concurrent with or after the subject has undergone primary treatment for said SCLC or neuroblastoma.

Group VI, claims 78 and 80 wherein the antibodies are administered to treat metastasis of said SCLC or neuroblastoma.

Group VII, claim 81 drawn to a method of treating infection by group B N. meningitides or E. coli KI comprising the administration of the said humanized antibodies of Group VI.

In the event applicant elects Group I, II, III, IV, or V the following requirement applies:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1, for reasons set forth above.

The species are as follows:

- a) immunogenic carrier, KLH, an immunogenic derivative of KLH
- b) bovine serum albumin (BSA) , an immunogenic derivative of BSA
- c) a promiscuous class II activating polypeptide or its immunogenic derivative

In the event of the election of Group I,II, III,IV or V applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

In the event applicant elects Group I, II, III, IV or V, the following election of species is required. The species are as follows:

- a. Saponin-QS-21
- b. Saponin- GPI 0100

In the event of the election of any of the above groups applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the instant claims lack unity of invention because the claims as a whole lack a special technical feature. As set forth above in view of the teachings of Jennings et al.(J Immunology ,1986,137: 1708-1713) the groups are not so linked to form a single general concept under PCT Rule 13.1, because the technical feature shared by Groups I-VII is not special.

The instant claims are drawn to different methods in Groups II, III, IV, V , VI and VII. The method of stimulating antibody production in Group II requires the step of administering an amount of the composition in Group I with modifications, which is not required for the claimed method of invention in Group VII. Conversely, Group III requires the composition in different molar ratios for the treatment of small cell lung carcinoma , which is not required for the claimed method of invention of Groups V and VI. Thus the inventions are patentably distinct.

Art Unit: 1642

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

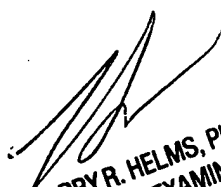
Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saraswathy Seetharam, PhD whose telephone number is 571-272-2113. The examiner can normally be reached between 8-4.30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER

Saraswathy Seetharam, PhD  
Examiner  
Art Unit 1642